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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 573

[Docket No. 98F–0195]

Food Additives Permitted in the Feed and Drinking Water of Animals; Menadione Nicotinamide Bisulfite

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of menadione nicotinamide bisulfite (MNB) in diets of growing and finishing swine as a nutritional supplement for the prevention of vitamin K deficiency and as a source of supplemental niacin. This action is in response to a food additive petition (animal use) filed by Vanetta S.p.A.

DATES: The regulation is effective (*insert date of publication in the* **Federal Register**); submit written objections and requests for a hearing by (*insert date 30 days after date of publication in the* **Federal Register**).

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Michaela G. Alewynse, Center for Veterinary Medicine (HFV–228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6657.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of May 12, 1998 (63 FR 26194), FDA announced that a food additive petition (animal use) (FAP 2239) had been

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filed by Vanetta S.p.A., Via Alzia Trento 10, Milano, Corsico, Italy. The petition proposed to amend the food additives regulations in part 573 (21 CFR part 573) to provide for use of menadione nicotinamide bisulfite in swine diets as a source of vitamin K activity and niacin. The notice of filing provided that written comments be sent to the Dockets Management Branch. No comments were received.

The agency has evaluated the information submitted by the sponsor in support of the petition and other relevant material and concluded that it establishes the safety and utility of up to 10 grams MNB per ton of complete feed in the diets of growing and finishing swine as a nutritional supplement for the prevention of vitamin K deficiency and as a source of supplemental niacin. Therefore, § 573.625 is amended to provide for this use. Furthermore, the section is revised to conform to current format.

In accordance with § 571.1(h) (21 CFR 571.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Center for Veterinary Medicine by appointment with the information contact person listed above. As provided in § 571.1(h), FDA will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has determined under 21 CFR 25.32(r) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Any person who will be adversely affected by this regulation may at any time on or before (*insert date 30 days after date of publication in the* **Federal Register**), file with the Dockets Management Branch (see above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. Each numbered objection on which a hearing is requested shall specifically so state. Failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each

numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held. Failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 573

Animal feeds, Food additives.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 573 is amended as follows:

PART 573—FOOD ADDITIVES PERMITTED IN FEED AND DRINKING WATER OF ANIMALS

1. The authority citation for 21 CFR part 573 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348.

2. Section 573.625 is revised to read as follows:

§ 573.625 Menadione nicotinamide bisulfite.

The food additive may be safely used as follows:

(a) The additive is 1,2,3,4-tetrahydro-2-methyl-1,4-dioxo-2-naphthalene sulfonic acid with 3-pyridine carboxylic acid amine (CAS No. 73581–79–0).

(b) The additive is used or intended for use as a nutritional supplement for both the prevention of vitamin K deficiency and as a source of supplemental niacin as follows:

(1) In chicken and turkey feeds at a level not to exceed 2 grams per ton of complete feed.

(2) In growing and finishing swine feeds at a level not to exceed 10 grams per ton of complete feed.

(c) To assure safe use, the label and labeling of the additive shall bear adequate directions for use.

Dated: 8/2/99
August 2, 1999

Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 99–???? Filed ??–??–99; 8:45 am]

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Mich W. Bell